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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ZALUKAEVA, TATYANA

ART UNIT PAPER NUMBER

1713

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/624,583

Applicant(s)

DOMSCHKE ET AL.

Examiner

Tatyana Zalukaeva

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>05/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No.

6,653,420. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims discloses identical process for the manufacture of a hydratable porous polymer comprising the steps of: (a) providing a homogeneous composition at a temperature below the cloud point temperature of the composition comprising (i) a polymerizable component that comprises at least one polymerizable hydrophilic monomer or macromer, (ii) a porogen having an inverse temperature dependent solubility and (iii) a solvent; (b) subjecting the composition to a polymerization reaction at a temperature around the cloud point temperature of the composition; and (c) removing the porogen from the resulting porous polymer at a temperature below the cloud point temperature of the composition.

Specification

3. The abstract of the disclosure is objected to because the abstract should be written as one paragraph with no intents and /or line spaces. Correction is required.
See MPEP § 608.01(b).
4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
5. Applicants are reminded that the continuity data should be updated.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claim1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recited in steps (b) and (c) polymerizing and removing the porogen at temperatures above and below the cloud point of a **composition** is not indefinite because it does not give a reasonable guidance to one skilled in the art as to what temperature is meant, the cloud temperature of a porogen, as described in the instant Specification on page 8, lines 5-20. The instant Specification merely mentions the cloud points of porogens (Pluronics) as being preferably between 30-100°C, or 30-40°C (page 6, lines 4-6, page 8, lines 5-20), however nothing is said about the “cloud point” of a

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composition, nor there is provided any guidance on how to determine the “cloud point”, of a composition.

The claim 11 is indefinite since undue experimentation is involved to determine boundaries of protection. This rationale is applicable to polymer “obtainable” by a stated process because any variation in any parameter within the scope of the claimed process would change the polymer produced. One who made or used a polymer made by a process other than the process cited in the claim would have to produce a polymer using all possible parameters within the scope of the claim, and then extensively analyze each product to determine if this polymer was obtainable by a process within the scope of the claimed process. Consult *Ex parte Tanksley*, 26 USPQ 2d 1389

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 6-9, 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hennink et al (U.S. 5,019,100).

Hennink discloses eye lens made of a polymer, which was prepared by a curing of a polymer network composed of polymethacrylate, which contains chemically bound

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ethylene oxide units, as hydratable groups to render the hydratability of a polymer, the ethylene oxide is in the form of oligomer blocks. (see abstract). The properties related to water permeability can be further modified by including other types of hydratable groups in the network, such as **N-vinylpyrrolidone** (col. 4, lines 31-44). The amount of ethylene oxide ranges from 10-80% by weight (col.4, lines 5,6) . The ethylene oxide units are presented in a form of oligomeric blocks containing 5-200 ethylene oxide units.

Especially interesting is an example 1 in col.8 both in terms of components taken for copolymerization, and the mode of the process.

This example relates to preparing a preparation for manufacturing **eye lenses** and also to manufacturing an eye lens. A preparation which consists of 43.8% by weight of PLURONIC PE 6400-IEM, (**PEO-PPO-PEO**) 38.2% by weight of NVP, 15.0% by weight of water, 2.0% by weight of QUANTACURE BTC and 1.0% by weight of antioxidant is introduced into a suitable glass mould . Subsequently, the mould is irradiated for 1.5 minutes with a conventional 2 kW high-pressure mercury lamp. Then the mould is turned over and is irradiated again for 1.5 minutes. The lens formed is removed from the mould and finally irradiated for 15 minutes once again to complete the polymerization. The lens thus obtained is subsequently subjected to the washing programme: (see col. 8, lines 25-41), which inherently removes the unreacted Pluronics

This swellability can be controlled by adding 0-45% by weight of water to PLURONIC PE 6400-IEM, the swellability of the **cured gel** can be accurately controlled to from 38 to 46% by weight. The process is performed at room temperature. Since the term "cloud point of a composition" is not defined or explained in the instant

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Specification, as stated in the rejection under 35 USC 112, second paragraph, it is believed that the temperature of Hennink satisfies the temperature as instantly claimed.

Therefore all the limitations of the instant claims 1-3, 6-9, 11-15 either expressly or inherently met by Hennink.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 4, 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Hennink et al (U.S. 5,019,100) in view of Kato et al (U.S. 4,529,747).

Hennink discloses the process as instantly claimed utilizing the comonomers as instantly claimed for the same purpose of producing intraocular lens as the Applicants'.

Hennink does not disclose:

- a) the use of low molecular weight crosslinker in a polymerization process
- b) not specifying the temperature of 30-40°C.

Kato discloses soft contact lenses made of a copolymer composed essentially of two comonomers 30-60 parts by weight of monomer (a) and 40-70 parts by weight of monomer, such as comonomer (b) N-vinylpyrrolidone, hydroxyalkyl acrylate and hydroxyalkyl methacrylate (col. 1, especially lines 50-68, col.3, lines 1-7), (b) and from about 0.05-2.0 parts by weight of crosslinking agent, wherein the water content in a copolymer is 25-50%. (see abstract, col. 1, lines 50-68, col. 2, lines 1-3). This amount of water content in a polymer inherently renders such polymer hydratable.

Suitable crosslinking agents are presented in col. 3, lines 29-37 and are identical to the crosslinking agents utilized in the instant invention as disclosed in the instant specification.

It is noted here that Hennink does utilize curing of the prepolymer by reacting it with a multifunctional acrylate as disclosed in col.5, lines 15-25, thus motivating one

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skilled in the art to utilize different crosslinkers, as well as their different amounts to achieve the desired network structure and swellability.

Since both Hennink and Kato produce similar oligomers for the same purpose, and since Hennink provides a clear suggestion of curing (crosslinking) his polymers, a person skilled in the art would have found it obvious at the time the invention was made to utilize the crosslinkers of Kato in the systems of Hennink in order to achieve the desired degree of swellability and water content.

With regard to the temperature of the process, which is claimed to be between 30-40°C, Hennink does not specify the temperature, however, Hennink utilizes the same initiators, as instantly claimed therefore his process needs essentially the same temperature in order to make an initiator active, furthermore, it is noted that discovery of optimum value of result effective variable in known process is ordinarily within the skill in the art and would have been obvious, *In re Boesch and Slaney* 205 USPQ 215 (CCPA 1980).

Therefore, combination of references renders claims 4, 5 and 10 prima facie obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tatyana Zalukaeva whose telephone number is (571) 272-1115. The examiner can normally be reached on 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tatyana Zalukaeva
Primary Examiner
Art Unit 1713

June 23, 2004

A handwritten signature in black ink, appearing to read 'Zalukaeva', with a long horizontal flourish extending to the right.